



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/635,818	08/05/2003	John Joseph Harrington	ATX-007CP4DV13CN	1411
959 7590 09/04/2007 LAHIVE & COCKFIELD, LLP ONE POST OFFICE SQUARE BOSTON, MA 02109-2127			EXAMINER CHEN, SHIN LIN	
			ART UNIT 1632	PAPER NUMBER
			MAIL DATE 09/04/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/635,818

Applicant(s)

HARRINGTON ET AL.

Examiner

Shin-Lin Chen

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 2-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 2-27 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |  |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                      | 5) <input type="checkbox"/> Notice of Informal Patent Application                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____  |

Art Unit: 1632

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 2-11, 22, 26 and 27, drawn to a eukaryotic cell in vitro comprising a vector comprising a first promoter operably linked to a nucleotide sequence encoding a selectable marker, and a second promoter operably linked to an unpaired splice donor, wherein the vector is non-homologously integrated into the genome of said eukaryotic cell to express a fusion transcript comprising the nucleotide sequence encoding the selectable marker and/or the unpaired splice donor and one or more exons of an endogenous gene, and the coding sequence in said endogenous gene is translated, a library of said eukaryotic cell, and said vector, wherein the eukaryotic cell is an animal cell, a fungal or a yeast cell, classified in classes 435 and 424, subclasses 320.1 and 93.21, respectively.
  - II. Claims 12, 17, 21 and 23, drawn to a vector comprising a first promoter operably linked to a nucleotide sequence encoding a selectable marker, and a second promoter operably linked to an unpaired splice donor, said vector further comprising one or more transposition signals, a eukaryotic cell in vitro comprising said vector, and a library of said eukaryotic cell in vitro, classified in classes 435 and 424, subclasses 320.1 and 93.21, respectively.
  - III. Claims 13-15, 18, 19, 21 and 23, drawn to a vector comprising a first promoter operably linked to a nucleotide sequence encoding a selectable marker, and a second promoter operably linked to an unpaired splice donor, said vector further comprising one or more viral origins of replication or viral replication factor genes, a eukaryotic cell in vitro comprising said vector, and a library of said

Art Unit: 1632

eukaryotic cell in vitro, classified in classes 435 and 424, subclasses 320.1 and 93.21, respectively.

- IV. Claims 16, 20, 21 and 23, drawn to a vector comprising a first promoter operably linked to a nucleotide sequence encoding a selectable marker, and a second promoter operably linked to an unpaired splice donor, said vector further comprising genomic DNA, a eukaryotic cell in vitro comprising said vector, and a library of said eukaryotic cell in vitro, classified in classes 435 and 424, subclasses 320.1 and 93.21, respectively.
- V. Claims 24 and 25, drawn to a method for increasing protein expression of an endogenous gene in a eukaryotic cell in vitro by introducing a vector into said eukaryotic cell, wherein said vector comprises a first promoter operably linked to a nucleotide sequence encoding a selectable marker, and a second promoter operably linked to an unpaired splice donor, wherein the vector is non-homologously integrated into the genome of said eukaryotic cell to express a fusion transcript comprising the nucleotide sequence encoding the selectable marker and/or the unpaired splice donor and one or more exons of an endogenous gene, and the coding sequence in said endogenous gene is translated, classified in class 435, subclass 69.1.

Claims 21 and 23 link(s) inventions II-IV. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 21 and 23. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the

Art Unit: 1632

allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also M.E.P. § 804.01.

The inventions are distinct, each from the other because of the following reasons:

2. Groups I-IV are patentably distinct from each other because they are drawn to different vectors that comprises different components and can work by different mechanisms and have distinct utilities. The vectors function differently in the eukaryotic cells. The search for those vectors would not be co-extensive. They are not obvious variants. Thus, groups I-IV are patentably distinct from each other.
3. Inventions I and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the vector of invention I can be used to produce the selectable marker rather than to increase protein expression of an endogenous gene. They have different classifications and require separate search. Thus, inventions I and V are patentably distinct from each other.

Art Unit: 1632

Groups II-IV and group V are unrelated because the vectors of groups II-IV are not used or otherwise involved in the method of group V. Thus, groups II-IV are patentably distinct from group V.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shin-Lin Chen whose telephone number is (571) 272-0726. The examiner can normally be reached on Monday to Friday from 9:30 am to 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272-4517. The fax phone number for this group is (571) 273-8300.


Art Unit: 1632

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Shin-Lin Chen, Ph.D.

  
**SHIN-LIN CHEN  
PRIMARY EXAMINER**